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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/478,882	01/07/2000	MARIKO EGAWA	TOS-125-USA-	2312

7590 05/07/2002

TOWNSEND & BANTA
1225 EYE STREET NW
SUITE 500
WASHINGTON, DC 20005

EXAMINER

BERMAN, ALYSIA

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 05/07/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/478,882	EGAWA ET AL.
Examiner	Art Unit	
Alysia Berman	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 06 February 2002 and 22 February 2002.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 1-10 and 12-16 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 11 and 17-25 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. 09/147,293.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) Paper No(s). <u>12</u> . |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 6, 2002 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 20 and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claims 20 and 25 are indefinite because it is unclear what Applicant intends to encompass by derivatives of hydroxycarboxylic acids. Neither the specification nor the claims gives an exclusive definition of the hydroxycarboxylic acid derivatives. The metes and bounds of the claims cannot be determined.

5. Claim 25 is indefinite because it contains the word, "appying" [sic].

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

7. Claims 17 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,601,806 (806).

US '806 discloses compositions for topical use that contain antioxidants such as thiotaureine (aminothiosulfonic acid). See column 1, lines 13-20, column 3, lines 43-50, column 4, lines 60-63 and example 1 at column 12. For application to the skin see the claims. For at least about 1 mmol/l of thiotaureine see Table 1 at the bottom of column 4.

8. Claims 11, 17, 20 and 23 are rejected under 35 U.S.C. 102(e) as being anticipated by US 5,747,049 (049).

US '049 is directed to cosmetic compositions containing an aminoethyl compound for topical application to treat and prevent cutaneous aging (abstract, column 1, lines 4-6 and the claims). For UV absorbers see column 2, lines 24-29, column 4, line 56 to column 5, line 40, the examples and claims 4, 10 and 17. For thiotaureine see column 3, lines 3-5 and the examples. For UV light blocking agents see column 5, lines 41-43 and column 10, line 51 to column 11, line 15. For a composition containing thiotaureine and a UV absorber see Table 2 at column 12, Table 3 bridging columns 13 and 14 and the formulation examples beginning at the bottom of column 14. For a

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composition containing thiotaureine, a UV absorber and 0.05 wt.% citric acid see Formulation Example 1 bridging columns 14 and 15.

9. The claims are directed to a method of applying a composition containing thiotaureine to the skin. Any properties exhibited by or benefits provided by application of the composition to the skin are inherent and are not given patentable weight over the prior art method of topical application. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990). See MPEP §2112.01. The burden is shifted to Applicant to show that the prior art product does not inherently possess the same properties as instantly claimed product. The prior art teaches application to the skin of compositions containing the same components as instantly claimed. Applicant has not provided any evidence of record to show that the prior art compositions do not exhibit the same properties as instantly claimed.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

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were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,601,806 (806).

US '806 teaches all the limitations of the claims as stated in the 35 U.S.C. 102(b) rejection above. It does not teach about 5 mmol/l of thiotaurine (claim 18). It is within the skill in the art to select optimal parameters in a composition in order to achieve a beneficial effect. *In re Boesch*, 205 USPQ 215 (CCPA 198). "It is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Only if the "results optimizing a variable" are "unexpectedly good" can a patent be obtained for the claimed critical range. *In re Antonie*, 559 F.2d 618, 620, 195 USPQ 6, 8 (CCPA 1977); see also *In re Dillon*, 919 F.2d 688, 692, 16 USPQ2d 1897, 1901 (Fed. Cir. 1990) (in banc). Therefore, absent evidence of unexpected results, the mmol/l of thiotaurine in the composition are not given patentable weight.

It would have been obvious to one of ordinary skill in the art at the time of the invention to vary the proportions of components in a composition of US '806 to arrive at the best compositions for the intended purpose of scavenging active oxygen compounds in order to prevent or minimize skin damage.

13. Claims 11 and 17-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,747, 049 (049).

US '049 teaches all the limitations of the claims as stated in the 35 U.S.C. 102(e) rejection above. It does not teach at least about 1 mmol/l of thiotaureine (claim 19), about 5 mmol/l of thiotaureine (claim 18), or a composition containing thiotaureine and a UV light-blocking agent (claims 24 and 25).

US '049 does teach that UV light blocking agents can be added to the composition (col. 4, lines 11-55 and to column 5, lines 41-43). Absent evidence of unexpected results, the mmol/l of thiotaureine in the composition are not given patentable weight. See above.

It would have been obvious to one of ordinary skill in the art at the time of the invention to prepare a composition containing thiotaureine, a UV absorber and citric acid as taught by US '049 and add a UV light blocking agent selecting optimal amounts of components with the reasonable expectation of obtaining a cosmetic composition that protects the skin from the damage caused by UV light exposure.

14. Claims 11 and 17-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over either US 5,601,806 (806) or US 5,747,049 (049) each in view of the other.

US '806 and US '049 teach all the limitations of the claims as stated in the 35 U.S.C. 102(b), 102(e) and 103(a) rejections above. Neither reference explicitly teaches a composition containing at least about 1 mmol/l of thiotaureine, a hydroxycarboxylic acid, a UV absorber and a UV light-blocking agent.

It is within the skill in the art to select optimal parameters of a composition in order to achieve a beneficial effect. Therefore, absent evidence of unexpected results, the mmol/l of thiotaurine in the composition are not given patentable weight. See above.

It would have been obvious to one of ordinary skill in the art at the time of the invention to prepare a composition containing thiotaurine, a hydroxycarboxylic acid, a UV absorber and a UV light blocking agent in optimal amounts as taught by US '806 in combination with US '049 with the reasonable expectation of obtaining an anti-aging cosmetic composition that provides protection against skin damage caused by exposure to UV light.

Unexpected Results

15. It is applicant's burden to demonstrate unexpected results over the closest prior art. See MPEP 716.02, also 716.02 (a) - (g). Furthermore, the unexpected results should be demonstrated with evidence that the differences in results are in fact unexpected and unobvious and of both statistical and practical significance. *Ex parte Gelles*, 22 USPQ2d 1318, 1319 (Bd. Pat. App. & Inter. 1992). Moreover, evidence as to any unexpected benefits must be "clear and convincing" *In re Lohr*, 137 USPQ 548 (CCPA 1963), and be of a scope reasonably commensurate with the scope of the subject matter claimed, *In re Linder*, 173 USPQ 356 (CCPA 1972).

In the instant case, no data comparing the instant invention with the closest prior art has been presented.

Response to Arguments

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16. Applicant's arguments filed February 6, 2002 have been fully considered but they are not persuasive.

17. Applicant argues that thiotaurine in the composition of US '806 would not be an effective antioxidant in the absence of light irradiation. This argument is not found persuasive for the reasons set forth above regarding chemicals and their properties. The claims are directed to a method of applying a composition containing thiotaurine to the skin. Any properties exhibited by the composition are inherent. US '806 clearly teaches that thiotaurine is an antioxidant. It is not seen how the prior art use of the same chemical compound as instantly claimed does not provide Applicants' result. No data has been presented to show that the instantly claimed invention behaves differently than the prior art.

Further, one would reasonably expect that a composition that is applied to the skin for the purpose of treating environmental stress due to exposure to automobile exhaust gases as instantly claimed would be exposed to light irradiation. It is reasonable to expect that exposure to automobile exhaust gases would occur outdoors while also being exposed to natural light. Additionally, people are exposed to light irradiation from other light sources while indoors. Therefore, Applicants' composition, when used as instantly claimed, would be exposed to light irradiation and would exhibit the same properties as the prior art.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alysia Berman whose telephone number is 703-308-

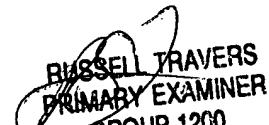
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4638. The examiner can normally be reached Monday through Friday between 9:00 am and 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, can be reached on 703-308-4612. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 or 703-872-9307 for after-final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234 or 703-308-1235.


Alycia Berman
Patent Examiner
April 29, 2002


RUSSELL TRAVERS
PRIMARY EXAMINER
GROUP 1200

Attachment for PTO-948 (Rev. 03/01, or earlier)

6/18/01

The below text replaces the pre-printed text under the heading, "Information on How to Effect Drawing Changes," on the back of the PTO-948 (Rev. 03/01, or earlier) form.

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

1. Correction of Informalities -- 37 CFR 1.85

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the Notice of Allowability. Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136(a) or (b) for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

2. Corrections other than Informalities Noted by Draftsperson on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

Timing of Corrections

Applicant is required to submit the drawing corrections within the time period set in the attached Office communication. See 37 CFR 1.85(a).

Failure to take corrective action within the set period will result in **ABANDONMENT** of the application.